UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,287	08/27/2003	Jack Saltiel	32001.UT	5496

7590 12/02/2005

Allen, Dyer, Doppelt, Milbrath & Gilchrist, P.A.
Suite 1401
255 South Orange Avenue
P.O. Box 3791
Orlando, FL 32802-3791

EXAMINER	
WONG, EDNA	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,287	SALTIEL, JACK	
	Examiner	Art Unit	
	Edna Wong	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This is in response to the Amendment dated November 1, 2005. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Specification

The disclosure has been objected to because of minor informalities.

The objection of the disclosure has been withdrawn in view of Applicant's amendment.

Claim Objections

Claim **6** has been objected to because of minor informalities.

The objection of claim 6 has been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

I. Claims **6-9** have been rejected under 35 U.S.C. 102(b) as being anticipated by **Stevens** (US Patent No. 4,686,023).

The rejection of claims 6-9 under 35 U.S.C. 102(b) as being anticipated by Stevens has been withdrawn in view of Applicant's amendment.

II. Claims **11, 13 and 14** have been rejected under 35 U.S.C. 102(b) as being

anticipated by **Stevens** (US Patent No. 4,686,023).

The rejection of claims 11, 13 and 14 under 35 U.S.C. 102(b) as being anticipated by Stevens has been withdrawn in view of Applicant's amendment.

III. Claims **24-28** have been rejected under 35 U.S.C. 102(b) as being anticipated by **Stevens** (US Patent No. 4,686,023).

The rejection of claims 24-28 under 35 U.S.C. 102(b) as being anticipated by Stevens is as applied in the Office Action dated September 6, 2005 and incorporated herein. The rejection has been maintained for the following reasons:

Applicants state that Stevens teaches the use of a photosensitizer in the second step of his method and requires at least the presence of anthracene in order to produce vitamin D by his irradiation method.

In response, claim 24 recites that the *first* irradiation step is carried out without a photosensitizer. Stevens teaches this, the first stage irradiation of 7-DHC or ergosterol is at wavelength 240-265 nm (col. 4, lines 23-49).

Claim 24 is open to using a photosensitizer in the *second* irradiation step.

Claim Rejections - 35 USC § 103

I. Claims **1-4** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023).

The rejection of claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over

Stevens has been withdrawn in view of Applicant's amendment.

II. Claim **5** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 1-4 above, and further in view of **Michishita et al.** (US Patent No. 6,902,654 B2).

The rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over Stevens as applied to claims 1-4 above, and further in view of Michishita et al. has been withdrawn in view of Applicant's amendment.

III. Claim **10** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 6-9 above, and further in view of **Michishita et al.** (US Patent No. 6,902,654 B2).

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Stevens as applied to claims 6-9 above, and further in view of Michishita et al. has been withdrawn in view of Applicant's amendment.

IV. Claims **12, 16 and 17** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 11, 13 and 14 above.

The rejection of claims 12, 16 and 17 under 35 U.S.C. 103(a) as being unpatentable over Stevens as applied to claims 11, 13 and 14 above has been

withdrawn in view of Applicant's amendment.

V. Claim **15** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 11, 13 and 14 above, and further in view of **Michishita et al.** (US Patent No. 6,902,654 B2).

The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Stevens as applied to claims 11, 13 and 14 above, and further in view of Michishita et al. has been withdrawn in view of Applicant's amendment.

VI. Claims **18-22** have been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023).

The rejection of claims 18-22 under 35 U.S.C. 103(a) as being unpatentable over Stevens is as applied in the Office Action dated September 6, 2005 and incorporated herein. The rejection has been maintained for the following reasons:

Applicants state that Stevens teaches the use of a photosensitizer in the second step of his method and requires at least the presence of anthracene in order to produce vitamin D by his irradiation method.

In response, claim 18 recites that the *first* irradiation step is carried out substantially free of a photosensitizer. Stevens teaches this, the first stage irradiation of 7-DHC or ergosterol is at wavelength 240-265 nm (col. 4, lines 23-49).

Claim 18 is open to using a photosensitizer in the *second* irradiation step.

VII. Claim **23** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 18-22 above, and further in view of **Michishita et al.** (US Patent No. 6,902,654 B2).

The rejection of claim 23 under 35 U.S.C. 103(a) as being unpatentable over Stevens as applied to claims 18-22 above, and further in view of Michishita et al. is as applied in the Office Action dated September 6, 2005 and incorporated herein. The rejection has been maintained for the reasons as discussed above.

Applicants' remarks have been fully considered but they are not deemed to be persuasive.

VIII. Claim **29** has been rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 24-28 above, and further in view of **Michishita et al.** (US Patent No. 6,902,654 B2).

The rejection of claim 29 under 35 U.S.C. 103(a) as being unpatentable over Stevens as applied to claims 24-28 above, and further in view of Michishita et al. is as applied in the Office Action dated September 6, 2005 and incorporated herein. The rejection has been maintained for the reasons as discussed above.

Applicants' remarks have been fully considered but they are not deemed to be persuasive.

Response to Amendment

Claim Objections

Claims **6, 17 and 18** are objected to because of the following informalities:

Claim 6

line 2, the word -- the -- should be inserted after the word "in".

Claim 17

line 1, the claim does not refer to a preceding claim. See MPEP § 608.01(n).

Claim 18

line 3, the word -- a -- should be inserted after the word "of" (first occurrence).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

I. Claims **1-29** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1

lines 6-7, recites "the reaction mixture containing no photosensitizer".

Claim 6

lines 2-3, recites "in absence of a photosensitizer".

Claim 11

lines 2, recites "essentially no photosensitizer".

Claim 18

lines 2-3, recites "substantially free of photosensitizer".

Claim 24

lines 2-3, recites "without a photosensitizer".

Applicant's specification does not disclose that the reaction mixture in either the first or second irradiation steps or in a single irradiation step contains no photosensitizer.

Applicant states that the non-use of photosensitizer is supported in the application as filed, as there is no mention of any photosensitizer being present in the reaction mixture. Accordingly, having fully disclosed the invention and its best mode,

Applicant suggests that it would be clear to those skilled in the art that no photosensitizer is required in the present method.

In response, Applicant has not shown possession of the currently amended claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See MPEP § 2163.02. The no mentioning of any photosensitizer being present in the reaction mixture would not have been a reasonable clarity that the reaction mixture contains no photosensitizer.

II. Claims **7 and 17** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7

line 1, "the first and second irradiations" lack antecedent basis. There is only one irradiating step recited in claim 6. Thus, there is only one irradiation.

Claim 17

line 1, "the ultraviolet spectra" lacks antecedent basis.

Claim Rejections - 35 USC § 102

Malatesta

I. Claims **6-9** are rejected under 35 U.S.C. 102(b) as being anticipated by **Malatesta et al.** (US Patent No. 4,388,242).

Malatesta teaches a process for producing previtamin D (= previtamin D_2 or previtamin D_3), the process comprising:

irradiating a reaction mixture containing provitamin D (= 7-dehydrocholesterol (7-DHC) or ergosterol) in the absence of a photosensitizer with light having a wavelength of approximately 240 to 265 nm (= 245-260 nm) [col. 1, lines 50-57] and with light having a wavelength of approximately from 300 to 330 nm (= 330-360 nm) [col. 1, lines 58-65].

The first and second irradiations are sequential (col. 1, line 50 to col. 2, line 1; and Fig. 1).

The reaction mixture further contains a solvent (= diethyl ether) [col. 2, lines 7-11].

The reaction mixture further contains an organic solvent (= diethyl ether) [col. 2, lines 7-11].

Since Malatesta teaches all of the limitations recited in the instant claims, the reference is deemed to be anticipatory.

II. Claims **11, 13 and 14** are rejected under 35 U.S.C. 102(b) as being anticipated

by **Malatesta et al.** (US Patent No. 4,388,242).

Malatesta teaches a process for producing previtamin D (= previtamin D_2 or previtamin D_3), the process comprising:

irradiating a reaction mixture containing tachysterol (= tachysterol$_2$ (approx. 75%)) [col. 1, lines 55-57] and essentially no photosensitizer with light having a wavelength of approximately from 300 to 330 nm (= 330-360 nm) [col. 1, lines 58-65].

The reaction mixture further contains a solvent (= diethyl ether) [col. 2, lines 7-11].

The reaction mixture further contains an organic solvent (= diethyl ether) [col. 2, lines 7-11].

Since Malatesta teaches all of the limitations recited in the instant claims, the reference is deemed to be anticipatory.

III. Claims **24-28** are rejected under 35 U.S.C. 102(b) as being anticipated by **Malatesta et al.** (US Patent No. 4,388,242).

Malatesta teaches a process for the production of vitamin D (col. 2, lines 1-3), the process comprising:

(a) a first irradiation of a reaction mixture containing provitamin D (= 7-dehydrocholesterol (7-DHC) or ergosterol) without a photosensitizer with light having a wavelength of approximately 250 to 265 nm (= 245-260 nm) [col. 1, lines 50-57]; and

(b) a second irradiation of the reaction mixture with light having a wavelength in

the range of 330 to 360 nm (col. 1, lines 58-65).

(c) heating (= thermolysis) the reaction mixture after the second irradiation (col. 2, lines 1-3).

The heating consists of a temperature not exceeding 100°C (= about 60°C) [col. 2, lines 23-26].

The first and second irradiations are sequential (col. 1, line 50 to col. 2, line 1; and Fig. 1).

The reaction mixture further contains a solvent (= diethyl ether) [col. 2, lines 7-11].

The reaction mixture further contains an organic solvent (= diethyl ether) [col. 2, lines 7-11].

Since Malatesta teaches all of the limitations recited in the instant claims, the reference is deemed to be anticipatory.

Claim Rejections - 35 USC § 103

Stevens

I. Claims **11-14 and 16-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023).

Stevens teaches a process for producing previtamin D (= previtamin D_3 or previtamin D_2), the process comprising:

irradiating a reaction mixture containing tachysterol (col. 3, line 65 to col. 4, line

2) with light having a wavelength of approximately from 300 to 330 nm (= in the 290-400 nm range) [col. 4, lines 32-49].

The reaction mixture further contains a solvent (col. 4, lines 50-53).

The reaction mixture further contains an organic solvent (col. 4, lines 50-53).

The method of Stevens differs from the instant invention because Stevens does not disclose the following:

a. Wherein the reaction mixture contains essentially no photosensitizer, as recited in claim 11.

b. Wherein said wavelength consist of 313 nm, as recited in claim 12.

c. A method of estimating the progress of the process of Claim 11, the method comprising:

(i) determining ultraviolet absorption spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol;

(ii) monitoring the ultraviolet absorption spectrum for the reaction mixture; and

(iii) estimating progress of the process by applying singular value decomposition analysis to the monitored ultraviolet spectrum of the reaction mixture compared to the ultraviolet spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol, as recited in claim 16.

d. Wherein the ultraviolet spectra are measured using light having

wavelengths from approximately 230 nm to approximately 340 nm, as recited in claim 17.

Regarding claim 11, Stevens teaches that the amount of anthracene which is present can be anywhere within the range of 0.001 g/L up to a saturated solution of anthracene in the chosen solvent (col. 4, lines 53-65).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the reaction mixture described by Stevens with wherein the reaction mixture contains essentially no photosensitizer because 0.001 g/L of anthracene would not have materially affected the basic and novel characteristic of Stevens' composition.

When Applicant contends that modifying components in the reference composition are excluded by the recitation of "containing essentially no", Applicant has the burden of showing the basic and novel characteristics of his composition, i.e., a showing that the introduction of these components would materially change the characteristics of Applicant's composition. *In re Lajarte* 337 F 2d 870, 143 USPQ 256 (CCPA 1964).

Regarding claim 12, Stevens teaches that the second stage is irradiated in the 290-400 nm range (col. 4, line 35).

It would have been obvious to one having ordinary skill in the art at the time the

invention was made to have modified the process described by Stevens with wherein said wavelength consist of 313 nm because where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP § 2144.05).

Regarding claim 16, Stevens teaches that Dauben et al. reported that on the basis of the spectral data of the four major irradiation products, the yield of vitamin D analogues should be maximized by using a first step, irradiation with light of either 254 nm or 300 nm wavelength, and a second step irradiation with light of wavelength 330 nm or greater (col. 2, lines 61-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process described by Stevens with a method of estimating the progress of the process of Claim 11, the method comprising:

(i) determining ultraviolet absorption spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol;

(ii) monitoring the ultraviolet absorption spectrum for the reaction mixture; and

(iii) estimating progress of the process by applying singular value decomposition analysis to the monitored ultraviolet spectrum of the reaction mixture compared to the ultraviolet spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol,

because the yield of vitamin D analogues would have been maximized as taught by Stevens (col. 2, lines 61-67).

Regarding claim 17, the invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process described by Stevens with wherein the ultraviolet spectra are measured using light having wavelengths from approximately 230 nm to approximately 340 nm because the wavelength is a result-effective variable and one skilled in the art has the skill to calculate the wavelength that would determine the success of the desired reaction to occur, absent evidence to the contrary. MPEP § 2141.03 and § 2144.05(b).

II. Claim **15** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stevens** (US Patent No. 4,686,023) as applied to claims 11-14 and 16-17 above, and further in view of **Michishita et al.** (US Patent No. 6,902,654 B2).

Stevens is as applied above and incorporated herein.

The process of Stevens differs from the instant invention because Stevens does not disclose wherein the reaction mixture further contains methanol.

Like Stevens, Michishita teaches forming previtamin D (col. 14, lines 9-16). Michishita teaches that the reaction solvent includes ether solvents such as diethyl ether; alcohol solvents such as methanol; hydrocarbon solvents and halogenated hydrocarbon solvents (col. 14, lines 17-24).

The invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the process described by Stevens with wherein the reaction mixture further contains methanol because methanol would have been functionally equivalent to use as the reaction solvent, in doing the same endeavor, as taught by Michishita (col. 14, lines 9-24).

Malatesta

III. Claims **1-4** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242).

Malatesta teaches a process for the production of previtamin D (= previtamin D_2 or previtamin D_3), the process comprising:

(a) a first irradiation of a reaction mixture containing provitamin D (= 7-dehydrocholesterol (7-DHC) or ergosterol) with light having a wavelength of approximately 254 nm (= 245-260 nm) [col. 1, line 50-57]; and

(b) a second irradiation of the reaction mixture with light having a wavelength in the range of 330 to 360 nm (col. 1, lines 58-65).

The first and second irradiations are sequential (col. 1, line 50 to col. 2, line 1; and Fig. 1).

The reaction mixture further contains a solvent (= diethyl ether) [col. 2, lines 7-11].

The reaction mixture further contains an organic solvent (= diethyl ether) [col. 2,

lines 7-11].

The method of Malatesta differs from the instant invention because Malatesta does not disclose wherein the light of the second irradiation has a wavelength of approximately 313 nm.

Malatesta teaches that the second irradiation is in the wavelength range of 330-360 nm (col. 1, lines 58-65).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the wavelength of the second irradiation described by Malatesta with wherein the light of the second irradiation has a wavelength of approximately 313 nm because where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP § 2144.05).

IV. Claim **5** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 1-4 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Malatesta is as applied above and incorporated herein.

The process of Malatesta differs from the instant invention because Malatesta does not disclose wherein the reaction mixture further contains methanol.

Like Malatesta, Michishita teaches process for the production of previtamin D

(col. 14, lines 9-16). Michishita teaches that the reaction solvent includes ether solvents such as diethyl ether; alcohol solvents such as methanol; hydrocarbon solvents and halogenated hydrocarbon solvents (col. 14, lines 17-24).

Malatesta teaches diethyl ether (col. 2, lines 7-11).

The invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the solvent described by Malatestra with wherein the reaction mixture further contains methanol because diethyl ether and methanol are functionally equivalent as reaction solvents in such processes as taught by Michishita (col. 14, lines 9-24).

V. Claim **10** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 6-9 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Malatesta is as applied above and incorporated herein.

The process of Malatesta differs from the instant invention because Malatesta does not disclose wherein the reaction mixture further contains methanol.

Like Malatesta, Michishita teaches process for the production of previtamin D (col. 14, lines 9-16). Michishita teaches that the reaction solvent includes ether solvents such as diethyl ether; alcohol solvents such as methanol; hydrocarbon solvents and halogenated hydrocarbon solvents (col. 14, lines 17-24).

Malatesta teaches diethyl ether (col. 2, lines 7-11).

The invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the solvent described by Malatestra with wherein the reaction mixture further contains methanol because diethyl ether and methanol are functionally equivalent as reaction solvents in such processes as taught by Michishita (col. 14, lines 9-24).

VI. Claim **12** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 11, 13 and 14 above.

Malatesta is as applied above and incorporated herein.

The process of Malatesta differs from the instant invention because Malatesta does not disclose wherein said wavelength consists of 313 nm.

Malatesta teaches that the second irradiation is in the wavelength range of 330-360 nm (col. 1, lines 58-65).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the wavelength of the second irradiation described by Malatesta with wherein the light of the second irradiation has a wavelength of approximately 313 nm because where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP § 2144.05).

VII. Claim **15** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 11, 13 and 14 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Malatesta is as applied above and incorporated herein.

The process of Malatesta differs from the instant invention because Malatesta does not disclose wherein the reaction mixture further contains methanol.

Like Malatesta, Michishita teaches process for the production of previtamin D (col. 14, lines 9-16). Michishita teaches that the reaction solvent includes ether solvents such as diethyl ether; alcohol solvents such as methanol; hydrocarbon solvents and halogenated hydrocarbon solvents (col. 14, lines 17-24).

Malatesta teaches diethyl ether (col. 2, lines 7-11).

The invention as a whole would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the solvent described by Malatestra with wherein the reaction mixture further contains methanol because diethyl ether and methanol are functionally equivalent as reaction solvents in such processes as taught by Michishita (col. 14, lines 9-24).

VIII. Claims **16 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 11, 13 and 14 above, and further in view of **Stevens** (US Patent No. 4,686,023).

Malatesta is as applied above and incorporated herein.

The process of Malatesta differs from the instant invention because Malatesta does not disclose the following:

a. A method of estimating the progress of the process of Claim 11, the method comprising:

(i) determining ultraviolet absorption spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol;

(ii) monitoring the ultraviolet absorption spectrum for the reaction mixture; and

(iii) estimating progress of the process by applying singular value decomposition analysis to the monitored ultraviolet spectrum of the reaction mixture compared to the ultraviolet spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol, as recited in claim 16.

b. Wherein the ultraviolet spectra are measured using light having wavelengths from approximately 230 nm to approximately 340 nm, as recited in claim 17.

Stevens teaches that Dauben et al. reported that on the basis of the spectral data of the four major irradiation products, the yield of vitamin D analogues should be maximized by using a first step, irradiation with light of either 254 nm or 300 nm wavelength, and a second step irradiation with light of wavelength 330 nm or greater (col. 2, lines 61-67).

It would have been obvious to one having ordinary skill in the art at the time the

invention was made to have modified the process described by Malatesta with a method of estimating the progress of the process of Claim 11, the method comprising:

(i) determining ultraviolet absorption spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol;

(ii) monitoring the ultraviolet absorption spectrum for the reaction mixture; and

(iii) estimating progress of the process by applying singular value decomposition analysis to the monitored ultraviolet spectrum of the reaction mixture compared to the ultraviolet spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol,

because the yield of vitamin D analogues would have been maximized as taught by Stevens (col. 2, lines 61-67).

IX. Claims **18-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242).

Malatesta is as applied above and incorporated herein.

Malatesta also teaches a process for production of vitamin D (col. 2, lines 1-3), the process comprising (c) heating (= thermolysis) the reaction mixture after the second irradiation (col. 2, lines 1-3).

The heating consists of a temperature not exceeding 100°C (= about 60°C) [col. 2, lines 23-26].

X. Claim **23** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 18-22 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Malatesta is as applied above and incorporated herein.

XI. Claim **29** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Malatesta et al.** (US Patent No. 4,388,242) as applied to claims 24-28 above, and further in view of **Michishita et al.** (US Patent no. 6,902,654 B2).

Malatesta is as applied above and incorporated herein.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edna Wong whose telephone number is (571) 272-1349. The examiner can normally be reached on Mon-Fri 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Edna Wong
Primary Examiner
Art Unit 1753

EW
November 23, 2005